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RE: Comments to Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673-01

Dear Dr. Vogl:

I would like to take this opportunity to express some of the major concerns presented by the Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. As chair of the American Association of Medical Review Officers, I can say that I have not received a significant number of written comments from MROs concerning the proposals, and silence may be viewed as an endorsement. I believe, however, that the minimal response from the MRO community reflects the understanding of most MROs that the proposed rules are not simply technical amendments, but rather represent fundamental political and policy decisions.

Drug testing procedures are inextricably integrated with legal and policy considerations. I believe that the concerns presented in this letter reflect the concerns of many or most MROs, but not all. To that degree, the comments can be viewed simply as information that should be considered in developing the federal policy.

I find it difficult to be critical of the proposed amendments, because for over 20 years I have been a strong supporter of drug testing as a method of control to reduce demand and mitigate the adverse impact of drug abuse on society. I have had a number of unique opportunities to work in this field. I have worked as a toxicologist, developing drug testing methods. I worked in what was at the time the country's leading drug testing laboratory as part of its management and as its corporate counsel. I have also worked as a technical and legal consultant to federal agencies and private employers. For the past 10 years I have had the opportunity to work with the medical community and other leading experts in the field, training physicians to be Medical Review Officers as the founder and chair of the

American Association of Medical Review Officers.

I have written in the *Medical Review Officer Handbook* that the two decades of urinalysis testing programs have made America a safer place to travel and work. I was reminded during the recent funeral and eulogies of President Reagan that another part of his significant legacy was the conception and implementation of federal workplace drug testing programs. This was a forward-thinking solution to the substance abuse crisis at the time. It was a sound response to the public consensus that substance abuse was the most pressing problem facing America. In the post 9/11 world, there is now a consensus that drug abuse is not the most pressing problem facing America. Paradoxically, effective drug testing programs are required as much in 2004 as they were back in 1984.

I. Specimen Validity

Unfortunately, the history of workplace drug testing includes prolonged periods of regulatory stagnation, with the result that urine drug testing is not as effective today as it was twenty years ago. This is largely due to the lack of a mandatory and comprehensive specimen validity strategy. The specimen validity rules finally published on April 13, 2004 are long overdue, and they represent a sound technical strategy for significantly reducing adulteration.

Invalid Tests

A general policy concern of the specimen validity rule is worth mentioning here, and that is the increased reporting of invalid tests. Employers have a difficult time interpreting the significance of an invalid test. An invalid test can be relatively benign, or it can be sinister. In general, the "invalid" designation will create a stigma for the donor. For better or worse, workplace urine drug testing has been a black-and-white, up-or-down, positive or negative process. Now we have the "do-over"—the invalid specimen where the donor must return to the collection site for an immediate observed collection.

I understand that these invalid specimens are "suspect" specimens, but using that rationale, how do we ignore the significant number of urine specimens that are found to actually have drugs in them below the administrative cutoff levels? From a scientific perspective, these below-cutoff specimens are as positive as those above the cutoff. Even with the existing cutoff levels, are these specimens not suspect specimens also? Yet there is no need to recollect. Why not?

There are and will always be technical limitations to what can be accomplished in any drug testing technology. As a matter of policy, I would encourage the minimization of invalid tests, which are ambiguous to employers. I would also eliminate the confusion created by a laboratory report that states that the specimen is both "positive" and "invalid." Where there is a positive result, or a finding of substitution or adulteration, why not simply state the specific cause for the "invalid" finding (e.g., the actual pH measurement) rather than the

generic and confusing term "invalid"? It is not hard to imagine a hearing officer, law judge or employer looking at a "positive – invalid" result and simply throwing out the whole laboratory report.

Lowering Cutoff Values

There is general support for the proposal to lower cutoff levels for amphetamine and cocaine. This represents a significant enhancement to the existing program.

I would also recommend lowering the cutoff levels for THC. Or alternatively, lower the cutoff levels for THC in dilute specimens. In the past, the issue of "passive inhalation" of marijuana smoke has been raised as the reason for not lowering the THC cutoffs. Lowering the cutoff level for THC in a dilute specimen does not increase the probability of "passive inhalation" as compared to the existing cutoff levels in "normal" specimens. There is a general consensus in the technical community that these measures would result in a significant increase in positive results.

On-Site Screening for Specimen Validity

Finally, it would seem that on-site screening of urine specimens for "specimen validity" would be a convenient way to immediately flag suspect specimens and trigger an observed collection. This on-site screening for adulterants presents its own policy and implementation issues; nevertheless, it is somewhat surprising that this concept is not even addressed in the proposed amendments.

II. Alternative Technologies

It is reassuring and exciting that the regulatory pipeline has become unplugged. At the same time, very little of what came out of the pipeline on April 13, 2004 appears to be ready for implementation. It is highly unlikely that any federal agency would adopt using oral fluids under the conditions outlined in the proposed rule, or take on the costs of implementing a point-of-collection test, or even gravitate toward sweat testing, except for monitoring an individual in a return-to-work program. Oral fluid and point-of-collection testing offer significant benefits to program managers and federal agencies, but not as conceived here. It is hoped that the technical and policy issues that require a donor to "spit" into a test tube, and then have the collector split the specimen, and the requirement to also collect a urine specimen can be resolved.

Hair Testing

What is left, and apparently it is warmly endorsed, is hair testing. There is no doubt that hair testing holds the promise of providing a powerful tool for the identification of drug use or exposure for a relatively long period of time—essentially the age of the hair segment being tested. Hair testing has been promoted not only as a method of identifying drug use but for revealing patterns of use by means of segmental analysis and the interpretation of

quantitative results. These are very seductive promises, but hair testing is not going to be a night of romance.

There have been and continue to be serious technical, legal, policy, and perhaps even ethical questions about how hair testing technology should be utilized. Many of these concerns are identified in the proposed amendment and essentially discounted. Given the seriousness of the concerns and the lack of definitive answers to the concerns raised in the rule itself, there can be little doubt that if the proposed hair testing rules are adopted substantially as written, there will be an extensive period of legal—specifically, constitutional—challenge.

As we all know, the federal government is subject to the constitutional limitations of the Fourth Amendment in respect to performing and/or requiring drug tests. Thus, drug testing practices that may be acceptable for a private employer may be unconstitutional when applied by the government. A good example of this is the private employer's practice of screening applicants or employees with an immunoassay screen and not providing any laboratory confirmation of these presumptive results or even the opportunity for the donor to provide a prescription as an alternative medical explanation to a Medical Review Officer. Even if throwing the occasional baby out with the wash water makes good business sense for a private employer, it does not pass constitutional muster when attempted by a government agency. For one thing, it is not reasonable.

So what are the constitutional issues presented by hair testing? If urine testing is okay, why shouldn't we believe that hair testing is acceptable also? Some of the essential elements required by the Supreme Court to carve out an exception to the Fourth Amendment for suspicionless searches, including urine testing, are the presence of a compelling government interest, the "reasonableness" of the search, the "effectiveness" of the search and an acceptable "level of intrusion."

There has simply not been an opportunity for the courts to decide whether the use of hair as a drug testing specimen meets the constitutional requirements of a governmentally mandated suspicionless test. There is universal agreement that public safety and national security are compelling government interests. But is there a compelling government interest in determining whether a job applicant for a clerical position used an illegal drug two months ago? Where is the data that supports this?

Actually, this is not the hard part of the constitutional challenge facing hair testing. First and perhaps foremost is the fundamental variability of hair as a drug testing specimen. All biological specimens exhibit a degree of variability between individuals and between collections. There is, though, no more variable a human toxicology specimen than human hair. For thousands of years, men and women have been grooming, styling, cleaning, straightening, curling, dyeing, bleaching, perfuming, conditioning, powdering and perming their hair. Much of this cosmetic treatment represents a chemical assault on the specimen, resulting in everything from burnt ends and brittle hair to coated hair, discolored hair and even hair loss.

Hair is highly stylized. Look around any room full of people. Both men and women invest heavily in the appearance of their hair. Men pay a lot to get some to grow. Hair follicle transplants are expensive, as are pharmacological treatments. Hair is not a waste product like urine. The claim that collecting a hair specimen is easy is only true in the morgue. The reality is that it is very difficult to collect hair without adversely impacting the cosmetic appearance of the donor.

A significant number of both men and women have closely cropped hair; does this mean that they enjoy a shorter detection time? The general rule seems to be that in any population, 10–25 percent of the donors will not have sufficient head hair to collect. Does this mean that a larger swath of hair must be cut from their scalps to have a sufficient quantity to test? There are incidents where companies have implemented hair tests, only to find the employees "protesting" by shaving their heads. Is this a refusal to test? Will this be allowed, or will there be a requirement to obtain hair from other sources? When the adulteration industry gins up its product line for adulterating hair, will employers have to create a list of prohibited products?

Over the years I have heard proponents of hair testing, and what can be referred to as the "anything goes" crowd, recommend that in the absence of sufficient head hair the collector should collect chest hair (presumably from men), arm hair, underarm hair, and even pubic hair. These recommendations have varied from laboratory to laboratory and over time. One year something is recommended, the next year it is not, and then it is recommended again. Where are you going to get a comparable length and amount of hair from a female donor? What does the collector report when no hair is available anywhere—"None is available"?

In the absence of individualized suspicion, obtaining hair specimens from alternative body sites is an offensive idea, and it is probably constitutionally repugnant as well. I know that employers do this today, but it is a different ballgame when the government mandates the testing. I do not think you have to be a constitutional scholar to understand that the collection of body hair, simply because a person may have short hair or no hair, can raise a serious question of invasiveness—particularly in a regulatory framework that would allow a federal agency to voluntarily "choose" hair or urine or sweat. It is true that urine is also invasive, yet it is illustrative to note that in the absence of individualized suspicion the donor is allowed privacy to provide the specimen. Thus, I appreciate HHS's restraint in not proposing the collection of hair from "alternative sites." However, without alternative sites, will suspicionless hair testing work? Even proponents of hair testing believe that hair testing becomes hobbled without alternative sites.

The Hobson's choice presented is to recommend hair testing with the requirement for alternative collection sites, which will not pass constitutional muster for governmentally mandated suspicionless testing, or to recommend hair testing without allowing for alternative sites, which is expensive and relatively ineffective.

The challenge to the constitutional viability of suspicionless employment hair testing is not

just limited to the intrinsic problems of collection without cosmetic insult, or of short hair and whether or not to go hunting alternative sites, or even the interference in the analytical procedures from treated hair. Plain, untreated long hair also presents an insidious variable as well, one that raises the most concern—the color variable. Hair color varies from individual to individual, family to family, and ethnic group to ethnic group. Hair color is genetically determined. As discussed in the proposed amendment, there is a well-established relationship between the color of hair and the concentration of drugs found in all of the *in vitro* and *in vivo* controlled animal and human studies that have been performed.

An elegant illustration of the profound differences in drug concentration and hair color is seen in the Rollins controlled-dose hair study. [The Effect of Hair Color on the Incorporation of Codeine into Human Hair. Rollins et al., *Journal of Analytical Toxicology, 27(8):545 (2003).*] In the Rollins study, 16 male and female volunteers with various hair colors were selected. Each subject received a 30 mg oral dose of codeine 3 times daily for 5 days (450 mg). The plasma concentration (ACU) for a single 30 mg dose of codeine was determined for each subject. Urine was collected for the 5 days of codeine administration. Hair was collected (cutting) before, and at weeks 4, 5, 6, and 7 after drug administration. As you know, the study carefully measured the amount of drug found in each individual's hair.

The published data showed that the individual with black hair had about 5 times more drug in her hair than the donor with brown hair, 10 times more drug than the donor with blond hair, and more than 15 times more drug than the redhead. The data also reveals that within the black hair subgroup, an American Indian had the highest concentration of drug—essentially 20 times the concentration of the redhead. This is not random variability; it is genetically based variability. The authors note: *"When a 500 pg/mg (0.5 ng/mg) cutoff is applied to these data, >80% of subjects with black hair receiving this therapeutic dose would be reported 'positive' for codeine,"* and *"When the same cutoff is applied to subjects with other hair colors (brown, blonde, red) none would be reported 'positive' for codeine."*

Who in HHS or the administration, or for that matter the Congress, is willing to sign on to a policy proposing that if an American Indian wants to work for the federal government he or she would be subject to a drug test with a functional cutoff level that is 15 to 20 times lower than his or her European counterpart? Can you imagine any federal agency setting up a background check for applicants that goes back one year for blond applicants and 10 years for applicants with black hair? Would the agency claim that it is not race bias, it is simply hair color bias?

This color bias issue is often obscured by the fact that the increased probability of identifying drugs in dark hair is not an issue of "false positives." Positive tests are positive tests. It is also true that hair testing does not single out African-Americans, since individuals of Mediterranean ancestry, Asians, Hispanics and American Indians are in the same dark hair class. This color bias does, however, raise a fundamental issue of equality

and fairness in employment standards. Could an employer implement a drug testing program using urine that only tested individuals with black hair, and survive a claim of discrimination? I can tell you that in over ten years of teaching physicians, there are few who do not appreciate the concern over this color bias, and fewer minority physicians who do not view all this as a veiled form of discrimination and disparate impact.

Social studies of population groups have concluded that the differences in positive rates between white and black populations are due to drug preferences and patterns of use. These studies do not address the ultimate question of what the very large differences in concentration between black and blond hair mean in terms of actual consumption of drug and the probability of detection by hair analysis. That is the study that must be done to address this issue.

The severe penalties of our nation's drug laws are currently viewed as having a discriminatory impact on minority communities. Chris Rock, the well-known African-American comic, states the very un-comic opinion that all drug laws are racist in nature. It is not just minorities who share this view. So how does the federal government lead the drug testing community in addressing this inflammatory issue? Is this moving drug testing forward in the public's mind? Is this building trust and confidence in the hearts and minds of the 95% of workers who are drug-free? Or is that no longer an issue? There needs to be funding of a broader study to understand the potential disparate impact of the well-established color bias, and a further policy analysis of how the benefits of hair testing can be realized.

A different legal issue, and a good example of a technology-driven policy, is the proposal to use hair for return-to-duty testing. No federal agency has a policy in place that states if an employee has a positive drug test they will be suspended for a minimum of 90 days. Yet under this proposed rule, a federal agency can require a hair test for return to duty, which effectively does the same thing.

The proposed rule states that drugs will be detected in hair for 90 days. So including the 7-10 day grow-out period of positive hair below the scalp, this effectively provides a 100-day period where the hair test would be inappropriate, and therefore a 100-day period where the employee could not be returned to work. This is one example of a technology-driven policy. If federal employees are paid while they are out of service, how many drug-using federal employees will be given a three-month paid vacation? In my view, this is not simply a change in technology but a change in the conditions of employment for federal employees._

Costs of Laboratory Certification for Hair Tests

Separate from the legal, political and public relations issues is the cost of hair testing. Hair testing requires a great deal of art and physical manipulation of the hair specimen in the laboratory; it does not appear that increased volume of hair testing will result in decreased costs. From a laboratory perspective, increased volumes, in the absence of robotics, will

present significant operational challenges, and maintaining quality will require vigorous effort by the management.

There exists a significant cost differential between hair testing, which is currently unregulated, and urine testing, which is heavily regulated. This cost differential will increase with the additional operational costs of inspections and various conditions of certification. The production and costs of quality control and proficiency specimens is significant. The base costs of inspection and developing a sound certification program will, in the absence of federal appropriations, be borne by the few laboratories who apply for certification. Establishing an equivalent level of certification oversight for hair testing as it exists for urine will cost hundreds of thousands of dollars.

Recommendation

Despite all of these flaws and limitations, I believe that hair testing and the hair collection, with the option of using alternative sites, may be a reasonable employment practice where the job has a legitimate requirement for an extensive and comprehensive background check, such as for police officers. (In this context, hair testing is similar to the limited use of polygraphs in employment hiring and investigations.) Outside of the workplace testing segment, hair testing is a useful tool in the courts and has great potential for use in substance abuse evaluations—particularly with at-risk adolescents.

In conclusion, I do not believe that it is in the best interest of hair testing to implement the proposed rules at this time. I do not believe that the government has the data available to adequately defend hair testing in a well-pled Fourth Amendment challenge based on our current understanding of the technology and process, even with the strong anti-drug sentiment of the federal judiciary.

III. Medical Review Officer Certification Proposals

In Subpart N of the proposed amendment, HHS states that it will establish who may serve as a Medical Review Officer. It establishes the requirement that the individual successfully complete an examination administered by a nationally recognized entity that certifies MROs or a subspecialty board for physicians performing a review of federal employee drug test results, which has been approved by the Secretary.

Subpart N also establishes the requirements for nationally recognized entities to seek and obtain approval by the Secretary to certify MROs or for subspecialty boards for physicians performing a review of federal employee drug test results to submit their qualifications and sample examination. The proposal goes on to state that based on this annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the Federal Register of those entities and boards that have been approved.

For over a decade, the Medical Review Officer certification process created and established by AAMRO has been regarded as remarkably successful in providing physicians with the

knowledge, expertise and guidance to fulfill their duties as MROs and to serve as expert consultants in the area of workplace drug and alcohol testing. The examination and recertification process has been regarded by the medical communities as a model of efficiency and efficacy in assuring that MROs are technically competent and understand the legal and regulatory framework and what is necessary to successfully support the divergent interests of the government, employers and American workers.

There are, however, concerns among MROs about the necessity of the new proposals to require certification and to oversee the MRO certification process. The first concern is that the added administrative burden on the boards would result in significantly higher costs. As will be discussed below, there are a host of issues that will contribute to higher costs.

But first, let's not forget that there are relatively few Medical Review Officers whom this rule actually covers—it covers only those MROs who work for federal agencies covering federal employees. In addition, there is no level of federal oversight of certification or certification boards, or review of exam items, or any guarantee that increasing training time would assure that any particular MRO in the federal employment program is in fact practicing in compliance with an agency's policy, the requirements of the Mandatory Guidelines, or the government's expectations.

A much more effective and much less expensive approach would be the annual audit of federal MRO records. This audit process has long been established for MROs who are working in nuclear utilities. Such an audit also sheds a great deal of light on the agency's program, the collection process, and management decisions.

For the private certified MRO, the additional costs of HHS requiring certification and the approval process of certification boards simply represents a subsidy for the federal program. In the National Laboratory Certification Program the costs of federal laboratory certification are underwritten to a large degree by private-sector drug testing. The benefit to the laboratories in the past has been their ability to market their federal certification to private-sector employers for private-sector testing. There is no benefit in the MRO market for an MRO to distinguish his or her professional certification as being "federally" approved.

Voluntary certification of physicians as Medical Review Officers has served to attract physicians with specific business or personal interests in workplace drug testing. The Department of Transportation requirement for ongoing CME training for MROs and the requirement for MROs to pass a national exam elegantly and essentially made certification a de facto standard without increasing costs and while maintaining the "voluntary" nature of this credentialing. The certification of certification and all of the intrinsic bureaucracy will have the effect of turning certification into another death-and-taxes process.

Another cost consideration that is important but perhaps not obvious is that when a physician fails the certification exam there may be some adverse business consequences. Failing an exam for a few may also bruise egos or harm reputations. In the early days of

certification, a physician threatened to sue AAMRO because he failed the exam. There was no real legal basis for the suit, for how do you sue over a voluntary certification that you can retake at no additional cost? It was not until it was clear to the physician that we would be forced to prove in court that he was not minimally competent to be an MRO that the issue resolved itself.

It is, however, a different legal ballgame when the government is going to approve the examination and the certification board, and then require certification. An MRO who fails the exam or is de-certified can seek legal review over the process. Who is going to pay for the board's legal costs—the private sector MRO, who in theory bills the employers?

The success of the AAMRO certification process is also attributable to the ongoing close relationship that has existed between AAMRO's faculty and HHS. There has been a great deal of open communication, both formal and informal, between AAMRO and the professional staff of the SAMHSA Division of Workplace Programs and the National Laboratory Certification Program.

The danger of what appears to be a benign and simple proposal to "approve" the certification board is that it threatens the open and cooperative nature of the relationship. A working partnership between the boards and SAMHSA may quickly transform into a regulator–regulatee relationship. Problems will have to be worked out through a more legalistic and political process. It's the same process that made the government designate "frozen french fries" a fresh vegetable.

Regardless of the final decision on this area of MRO certification, and regardless of whether alternative testing becomes a reality for federal agencies in the near future, beginning next year AAMRO will include what up until now has been optional—training in alternative technologies. AAMRO will also incorporate the subject matter into its examination as part of the basic certification process.

Finally, as in any large group there will be some bad examples. Over a fourteen-year time frame and certification of thousands of MROs, there have been a few problems. Substance abuse has ironically been a problem. Mental illness has struck. Ethics, or more accurately the absence of ethics, has been discovered. We have occasionally been asked to "de-certify" an identified bad actor (about three). As desirous as that may have been, AAMRO is not set up to address that issue. Oversight of certification would not address these issues either. As soon as you begin a de-certification process, you become the reporting agency for every positive donor with an ax to grind—and a lot of them do have axes. Will HHS post its telephone number to handle donor complaints?

What will work is for HHS to adopt a process similar to DOT's "public interest exclusion" for the few identified bad actors. This list would be made up of MROs who would be excluded from providing any services to a federal agency or regulated employer. AAMRO will be happy to post that list on its website. This list would give employers, the courts, and interested parties adequate notice of problems.

Readers of these comments must think, if these comments in respect to the proposed rule represent an example of a good working relationship with the government, what is a bad one like? A bad one is where there is no open communication.

In closing, I would like to share my observation and opinion that the technical staff at the SAMHSA Division of Workplace Programs is composed of dedicated professionals who have shown nothing but a passion for overcoming the numerous legal, technical, political and social challenges to developing a balanced and cost-effective model for containing and managing drug abuse in America.

This is the first significant drug testing rulemaking since the inception of the program. I have little doubt that the administration is committed to maintaining the integrity of the program. I hope these comments are useful in shaping the department's final analysis, and that the advances in drug testing technology can be more seamlessly integrated into the legal framework and social policy goals than is reflected in this first attempt.

I am acutely aware of the current shortcomings in testing, and the technical and legal limitations imposed. I nevertheless continue to maintain the hope that sound drug testing programs may someday offer a substantive alternative to the evils intrinsic to prohibition by reducing demand and providing early intervention and thus more effective treatment. My hope is that drug testing can be an effective alternative to the high economic and social costs of the criminal justice system. I hope that these comments are viewed as constructive criticism.

Sincerely,

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